

REMARKS/ARGUMENTS

Claim 6 is pending with the entry of this Amendment. Claims 1 and 5 have been canceled without prejudice. No new matter has been added with the present Amendment.

Claim Rejection under U.S.C. § 112:

Claims 1 and 5 are rejected under 35 U.S.C. § 112, first paragraph, allegedly on the basis that the Specification, while being enabling for a method for preparing a factor VIII molecule having modified glycosylation specifically disclosed therein, does not reasonably provide enablement for a method for preparing a factor VIII protein having modified glycosylation comprising making a mutation anywhere in the protein sequence or anywhere in the A2 or C2 domains to insert a glycosylation site. Applicant respectfully traverses the rejection.

Applicant still maintains that the invention as claimed in claims 1 and 5 can be made and used by those of ordinary skill based on the disclosure provided herein combined with the knowledge available in the art. The Specification provides an example of how the invention can be practiced. All the necessary steps involved are routine, not undue, to those skilled in the art. The level of the skill and the knowledge in the relevant art (i.e., molecular biology and biochemistry) is high and all the necessary protocols are readily available to one of ordinary skill in the art to make and use the invention. It is clearly defined in all the claims that a modified factor VIII produced according to the invention be biologically active. The biological activity of a newly

produced factor VIII can be easily measured by employing one of many available assays in the art. One skilled in the art would not need further guidance or direction to practice the invention.

Claim 5 is further rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant respectfully traverses the rejection. Without acquiescing to various aspects of the rejection and in the interest of advancing the prosecution of this application, claims 1 and 5 have been canceled without prejudice.

In view of the foregoing amendments and remarks, withdrawal of the rejection under 35 U.S.C. § 112 is respectfully requested.

Conclusion:

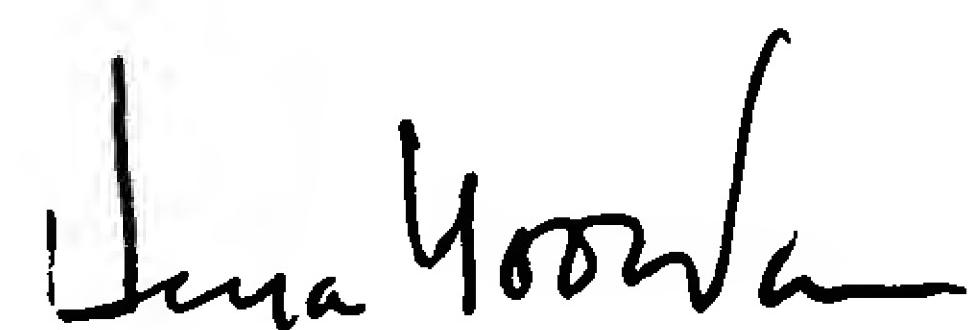
The Office Action indicated that claim 6 as previously presented was deemed allowable. Based on the foregoing amendments and arguments, this case is considered to be in condition for allowance and passage to issuance is respectfully requested.

If there are any outstanding issues related to patentability, the courtesy of a telephone interview is requested, and the Examiner is invited to call to arrange a mutually convenient time.

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Reply to Office Action of Nov. 5, 2003

It is believed that no fee is due with this submission; however, if this is incorrect, please deduct the appropriate fee for this submission and any extension of time required from Deposit Account No. 07-1969.

Respectfully submitted,



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